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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/598,479

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EXAMINER

LIN, JERRY

ART UNIT

PAPER NUMBER

1631

MAIL DATE

DELIVERY MODE

08/31/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/598,479	Applicant(s) BACHELER ET AL.	
	Examiner JERRY LIN	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 2,5,7,8 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6,9-22,24 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Species B and subspecies (ii) in the reply filed on June 11, 2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 2, 5, 7, 8, and 23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Status of the Claims

Claims 1, 3, 4, 6, 9-22, 24 and 25 are under examination.

Claims 2, 5, 7, 8, and 23 are withdrawn as being drawn to a non-elected claim.

Claim Rejections - 35 USC § 112, 2nd Paragraph

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 contains the trademark/trade name Virtual Phenotype System. Where a trademark or trade name is used in a claim as a limitation to identify or describe a

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particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a calculation method and, accordingly, the identification/description is indefinite.

Instant claims claim 21 recites that the the method of claim 1 may be used for assessing efficiency or for evaluating or optimizing a therapy. The language in the instant claim recites intended use of the method, but the instant claim does not appear to recite any further limitations of the parent claim nor does the instant claim recite any further method steps. Thus, it is unclear as to the metes and bounds of the instant claim.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 3, 4, 6, 9-22, 24 and 25 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

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The instant claims recite a series of mathematical steps for a diagnostic method. The method does not recite a physical transformation of matter nor are they tied to a particular machine. Furthermore, the mathematical steps are abstract idea. As an abstract idea, the instant claims are non-statutory.

Instant claim 24 recites a computer-based system. A system may be interpreted to include a process. Thus claim 24 may be interpreted as a computer process, which does not tie the instant claim as a machine and the claimed method remains an abstract idea.

Instant claim 25 recites a computer program product on a computer readable storage medium. A computer readable medium is interpreted as carrier wave which may transiently store data. However, carrier waves are non-statutory. Thus the instant claims are non-statutory.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 9, 11, 14-20, 22, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Harrigan et al. (AIDS (2001) volume 15, pages 1671-1677).

The instant claims are drawn to a method of comparing the fold change resistance value of a pathogen to a clinical cut-off value where the cut-off value is established by modeling the clinical response of a population.

Regarding claims 1 and 22, Harrigan et al. teach a method that includes obtaining a genetic sequence (page 1672, right column, under "HIV RNA extraction and genotyping"); identifying at least one mutation (page 1672, right column, under "Determination of virtual phenotype"); a genotype database (page 1672, right column, under "Determination of virtual phenotype"); a phenotype database (page 1672, right column, under "Determination of virtual phenotype"); a clinical response database (page 1673, left column, top paragraph); a correlation means for correlating a genotype entry with a phenotype (page 1672, right column, under "Determination of virtual phenotype"); a means of modeling clinical response to a drug of a disease (pages 1673 and 1674, under "Determination of new resistance cut-off values for antiretroviral drugs" and under "Prevalence of resistance using a 4-fold cut-off and new biological, and Virtual Phenotype cut-offs"); and predicting the clinical response (page 1676, left column and right column, bottom paragraph).

Regarding claim 3 and 4, Harrigan et al. teach where the cut-off value is calculated by a log pathogen load drop (pages 1673 and 1674, Figure 2 and under "Determination of new resistance cut-off values for antiretroviral drugs" and under "Prevalence of resistance using a 4-fold cut-off and new biological, and Virtual Phenotype cut-offs").

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Regarding claims 9 and 11, Harrigan et al. teach where the cut-off fold change resistance is calculated by reference to having an undetectable pathogen load after treatment (page 1674, left column).

Regarding claims 14, 15, 24 and 25, Harrigan et al. teach where the method is computer implemented (Use of the Virco relational database would require a computer system with computer software) (page 1672, right column, under "Determination of virtual phenotype").

Regarding claims 16-18, Harrigan et al. teach where the method uses a plasma sample to study HIV (page 1672, left column, under "Patients and samples").

Regarding claims 19 and 20, where a number of candidate drugs are assessed (abstract).

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY LIN whose telephone number is (571)272-2561. The examiner can normally be reached on 7:30-6:00pm, M-TH.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jerry Lin/
Primary Examiner, Art Unit 1631
8/29/2010